VHA Handbook 1200.05 (version dated 11/12/14)
Requirements for the Protection of Human Subjects in Research

Soundia Duche, MA, MS
Management and Program Analyst
Office of Research and Development

9 December 2014
Presentation Outline

- Key Highlights
- Executive Order 13563
- Impact on Facility
- Revisions to the Handbook
  - Deleted, no longer required
  - Gone, but not forgotten
  - Changed, no longer the same
- Questions/Comments
- Available Resources
Key Highlights – VHA Handbook 1200.05 (11/12/2014)

- Effective Date: November 12, 2014
- Implementation Date: March 12, 2015 (120 days post release date)
- Number of Paragraphs: 30
- Number of Pages: 36
- Why the significant revision?
  - Executive Order 13563
Executive Order 13563

- President Obama issued Executive Order 13563 on January 18, 2011, “Improving Regulation and Regulatory Review”

- Agencies mandated to identify and use the best, most innovative and least burdensome tools for achieving regulatory ends
  - Agencies required to review existing regulatory requirements that may be outmoded, ineffective, insufficient or excessively burdensome and modify, streamline, expand or repeal them as appropriate
Impact on Facility
How will my facility be impacted?

• Will our IRB need to re-review existing research?
• Will our IRB need to update all SOPs?
• What about upcoming ORO site visits?
• What exactly has changed in the new handbook?
Will our IRB need to re-review existing research?

- Previously approved research is subject to the requirements outlined in the previous version of the handbook (dated 5/2/2012) and does not have to be re-reviewed.
- Research approved during the 120-day implementation period is subject to the requirements outlined in each facility’s SOPs at the time of review.
Does our IRB need to update all SOPs?

- SOPs governing VA research cannot contradict requirements outlined in the revised VHA Handbook 1200.05
- VA research programs can choose to retain stricter requirements than outlined in the revised handbook where it makes sense to do so
- In order to implement new practices allowed by the revised handbook, relevant SOPs need to be changed prior to implementing new policies and procedures
What about upcoming ORO site visits?

- VA facilities and affiliates have until March 12, 2015, to implement the requirements outlined in the revised handbook
- ORO formally notifies VA facilities of upcoming site visits approximately six to eight weeks prior to a visit
- ORO does not expect sites to have revised all relevant SOPs before March 12, 2015, and will review research programs based on the SOPs in effect at the time of the site visit
- ORO will provide guidance to sites, visited during the 120-day implementation period, that may have already begun implementing some of the new requirements outlined in the revised handbook
What has changed in the revised handbook?

Three broad categories of revisions:

• Requirements that have been deleted and are no longer required by ORD
• Requirements that are no longer found in the handbook, but continue to be required by other VHA Directives, VHA Handbooks, or Federal Regulations
• Requirements that have changed
Deleted, no longer required
Deleted, no longer required

- Investigator subject outreach activities
- Creation and maintenance of a master list of subjects enrolled in VA research
- Flagging health records

1. Paragraph 5m in May 2012 version of handbook; 2. Paragraph 9i(1)(h) in May 2012 version of handbook
3. Paragraph 59 in May 2012 version of handbook
Deleted, no longer required (continued)

• IRB meeting minutes no longer have to be signed\(^1\)
• Notification letters to investigators (e.g., approval/disapproval letters) no longer have to be signed by the IRB Chair or a voting member of the IRB\(^2\)
• A timeframe for completion of draft IRB meeting minutes is no longer specified\(^1\)
• Annual Evaluation of HRPP Program\(^3\)
• IRB Audits\(^4\)

---

Gone, but not forgotten
The following requirements have been removed from the revised VHA Handbook 1200.05 but continue to be addressed in other policy documents:

- **Paragraph 42 on Serious Adverse Events**
  - Addressed in VHA Handbook 1058.01, Research Compliance Reporting Requirements
- **Paragraphs 50 and 51 on Engagement in Research/Human Subjects Research**
- **Paragraph 53 on Human Biological Specimens**
- **Paragraph 54 on Human Data**
  - Addressed in VHA Handbook 1200.12, Use of Data and Data Repositories in Research
Gone, but not forgotten (continued)

• Paragraph 8b on Appointment of local site liaison to VA Central IRB
  – Addressed in VA Central IRB SOP 101
• Paragraph 62c on Research Scope of Practice for VA Investigators and Research Staff
  – Addressed in VHA Directive 1200
• Paragraph 41 on Emergency Use of a Test Article
  – Addressed in FDA regulations
  – VHA does not conduct planned emergency research
• Paragraph 59 on IRB Review of Subject payments
  – Addressed in Common Rule Requirements (38 CFR 16.116)
  – IRBs must continue to ensure subject payments do not present undue influence, however additional VA-specific requirements have been removed
Changed, no longer the same
VA Facilities are now allowed to post/distribute advertisements for research related to Veterans that is not taking place at the VA. A procedure must be in place to review and approve the documents prior to posting\textsuperscript{1,2}

1. Paragraph 5b(5) in November 2014 version of Handbook; 2. See ORD’s guidance on Advertisement of Non-VA funded research in VA facilities
Exempt Research Determinations

• In addition to the IRB Chair and an experienced IRB voting member, exempt determinations can now also be made by IRB administrators and staff with appropriate training and background to make determinations

1. See ORD guidance document on Exempt Determinations.
A VA facility can now also designated the IRB of another Federal agency as its IRB of record.

- List of appropriate IRBs of records for VA facilities now include the facility’s own IRB; the IRB of another VA facility; the VA Central IRB; the IRB of its affiliated medical or dental school; and/or the IRB of another Federal agency

Approval from the CRADO continues to be required to add/change a designated IRB of record

An MOU between the two institutions must be signed outlining responsibilities

ORD, ORO and NCI are currently in negotiations to enable sites to use the NCI Central IRB for certain studies.

1. Paragraph 5d(1) in November 2014 version of the handbook.
IRB Membership

- The appointment term for IRB Chairs has been increased from one year to up to three years, renewable indefinitely\(^1\)
- VA Facilities with less than 10 active protocols can appoint one voting member and one alternate to the facility’s designated external IRB\(^2\)
- VA Facilities with 10 or more active protocols must continue to appoint two voting members to the facility’s designated external IRB\(^2\)
- Voting members appointed to the facility’s designated external IRB
  - Can now have only 1/8\(^{th}\) VA appointment (as opposed to 5/8ths previously)
  - Can both be considered “non-scientific members”\(^2\) (previously at least one member had to be a “scientific member”)

---

1. Paragraph 6n(2) in November 2014 version of the handbook; 2. Paragraph 5d(2)(b) in November 2014 version of the handbook

*VETERANS HEALTH ADMINISTRATION*
ISO/PO Reviews

- Information Security Officers (ISOs) and Privacy Officers (POs) may either serve as non-voting members or as advisory members to the IRB
- ISO/PO final review/signoff is not due until after IRB approval
- VA facilities are given flexibility to create arrangements for ISO and PO review that meet the requirements for ISO/PO signoff. For example, a facility could have a data security subcommittee that reviews all protocols.

1. Paragraph 22e in November 2014 version of the handbook
VA Form 10-3203

- VA Form 10-3203 (Consent for production and use of verbal or written statements, photographs, digital images, and/or video and audio recordings by the VA) is no longer required\(^1\)
  - The approved consent form must include information describing whether any photographs, video, and/or audio recordings will be obtained for research purposes.

---

1. Paragraph 16f in November 2014 version of the handbook
Documentation of Informed Consent

• Use of VA Form 10-1086, Research Consent Form, to document informed consent is no longer required\(^1\)
• The approved consent form must continue to indicate the date of IRB approval, however, each page no longer needs to be stamped\(^2\)
• If no physical contact with the subject will occur, the IRB can waive the signature of the individual obtaining consent \(^3\)
• Consent may be obtained electronically, so long as the informed consent process meets all requirements in paragraph 16 of the handbook\(^4\)

---

1. Paragraph 16a; 2. Paragraph 16e; 3. Paragraph 16e(2)(b); 4. Paragraph 16e(2)(c) in November 2014 version of the handbook

VETERANS HEALTH ADMINISTRATION
VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research, must be used for HIPAA authorizations for new studies

1. Paragraph 23
Student Research

- Students/trainees cannot serve as Principal Investigators for VA studies\(^1\)
- Students/trainees can only participate as a member of the VA research team if:
  - They are enrolled in an institution with an educational affiliation agreement with that VA facility, or
  - They are directly appointed to a VA training program that has no external institutional sponsorship (e.g., VA Advanced Fellowship)

\(^1\) Paragraph 28 in November 2014 version of the handbook
Training for Investigators

- Training in ethical principles on which human subjects research is to be conducted can now be completed every three years (as opposed to every two years)
- Good Clinical Practice (GCP) training is no longer required
- The Facility’s ACOS/R; AO/R; or R&D Coordinator can contact Alice Huang to change required training intervals and/or to delete GCP modules from your facility’s curriculum in CITI: alice.huang@va.gov

See http://www.research.va.gov/pride/training/default.cfm
## Waivers vs. Facility Director Approval

<table>
<thead>
<tr>
<th>Research Type</th>
<th>CRADO Waiver</th>
<th>Facility Director Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Research&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Required for Cooperative Studies only</td>
<td>Required for all other studies</td>
</tr>
<tr>
<td>Research involving Children&lt;sup&gt;2&lt;/sup&gt;</td>
<td>NA</td>
<td>Required</td>
</tr>
<tr>
<td>Researching involving Prisoners</td>
<td>Required</td>
<td>NA</td>
</tr>
<tr>
<td>Women of child bearing potential using pregnancy Category D or X drugs</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Research involving Pregnant Women&lt;sup&gt;3,4&lt;/sup&gt;</td>
<td>NA</td>
<td>Required</td>
</tr>
</tbody>
</table>

1. See ORD Guidance on Approval of International Research; 2. See ORD Guidance on Conducting Research Involving Children; 3. Greater than minimal risk interventions on pregnant women; 4. See ORD Guidance on Conducting Research Involving Pregnant Women
Streamlined and New Topics

The following topics have been streamlined significantly in the revised handbook:
• Collaborative Research\textsuperscript{1}
• Continuing Review\textsuperscript{2}
• IRB Meeting minutes\textsuperscript{3}

The following topic is a new addition to the handbook:
• Certificates of Confidentiality\textsuperscript{4}

\textsuperscript{1} Paragraph 13; \textsuperscript{2} Paragraph 8e; \textsuperscript{3} Paragraph 7c; and \textsuperscript{4} Paragraph 21 in November 2014 version of handbook
Questions/Comments
Where can I go if I have questions?

- Questions on the revised handbook should be submitted to the ORD regulatory mailbox: vhacoordregulatory@va.gov
- ORD plans to hold a total of six cyberseminars to discuss the changes to the handbook
  - Two will be repeat live sessions of today’s presentation
  - Three will be Q&A sessions to respond to questions submitted to the ORD regulatory mailbox
Available Resources
Available Resources

• Crosswalk between current version and 5/2/12 version of the handbook
• Summary of significant changes
• Scheduled cyberseminars

  VHA Handbook 1200.05 Rollout          VHA Handbook 1200.05 Mailbox Q&A
    • Tuesday, December 9th @ 2:30pm EST  • January 2015 – date/time TBD
    • Thursday, December 11th @ 2:30pm EST  • January 2015 - date/time TBD
    • Monday, December 15th @ 2:30pm EST    • January 2015 - date/time TBD

• Recently released ORD guidance documents

See:  http://www.research.va.gov/pride/default.cfm
Available Resources (continued)

Recently released ORD guidance documents:

- Guidance on Advertisement of Non-VA Funded Research in VA Facilities (10/20/2014)
- Guidance on Approval of International Research (10/20/2014)
- Guidance on Conducting Research involving Children (10/20/2014)
- Guidance on Conducting Research involving Pregnant Women (10/20/2014)
- Guidance on Continuing Review (10/22/2014)
- Guidance on Exempt Research Determination (10/20/2014)

http://www.research.va.gov/resources/policies/default.cfm
<table>
<thead>
<tr>
<th>Topics (listed alphabetically)</th>
<th>Paragraph in 1200.05 version 11/12/2014</th>
<th>Paragraph in 1200.05 version 5/2/2012</th>
<th>Summary &amp; Rationale for Significant Change in VHA Handbook 1200.05 (November 12, 2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advertisements: Posting/Distribution of ads for Non-VA research</strong></td>
<td>5b(5)</td>
<td>5n</td>
<td>VA facilities may now post/distribute advertisements and recruitment documents for other federally-funded research that is not taking place at a VA facility provided a procedure is in place to review and approve the documents prior to posting. For additional information, please refer to ORD’s guidance document on Advertisement of Non-VA Funded Research in VA Facilities.</td>
</tr>
<tr>
<td><strong>Certificates of Confidentiality</strong></td>
<td>21</td>
<td>NA</td>
<td>New addition to handbook. For additional information, please refer to <a href="http://www.grants.nih.gov/grants/policy/coc/index.htm">http://www.grants.nih.gov/grants/policy/coc/index.htm</a></td>
</tr>
<tr>
<td><strong>Children</strong></td>
<td>19a</td>
<td>48a</td>
<td>A waiver from the CRADO to conduct research on children is no longer required. Instead, approval from the Facility Director must be obtained prior to the conduct of research involving children at the VA. For additional information on this topic, please refer to ORD’s guidance document on Conducting Research Involving Children.</td>
</tr>
<tr>
<td><strong>Collaborative Research</strong></td>
<td>13</td>
<td>52</td>
<td>Requirements have been streamlined significantly.</td>
</tr>
<tr>
<td><strong>Continuing Review</strong></td>
<td>8e</td>
<td>22</td>
<td>Requirements have been streamlined to be more consistent with the Common Rule. For additional information, please refer to ORD’s guidance document on continuing review.</td>
</tr>
<tr>
<td><strong>Emergency Use of a Test Article</strong></td>
<td>NA</td>
<td>41</td>
<td>Deleted from handbook.</td>
</tr>
<tr>
<td><strong>Engagement in Research/Human Subjects Research</strong></td>
<td>NA</td>
<td>50 &amp; 51</td>
<td>Deleted from handbook.</td>
</tr>
<tr>
<td><strong>Exempt Research</strong></td>
<td>NA</td>
<td>16</td>
<td>In addition to the IRB Chair and an experienced voting member of the IRB, ORD now allows IRB administrators or IRB staff who have appropriate training and experience to make exempt determinations. For additional information on this topic, please refer to ORD’s guidance document on Exempt Research Determination.</td>
</tr>
<tr>
<td><strong>Facility Director Responsibilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointment of local site liaison to the VA Central IRB</td>
<td>NA</td>
<td>8b</td>
<td>Deleted from handbook as ORD requirement; required by VA Central IRB SOPs.</td>
</tr>
<tr>
<td>Annual Evaluation of HRPP program</td>
<td>NA</td>
<td>6c</td>
<td>Deleted from handbook as ORD requirement.</td>
</tr>
<tr>
<td><strong>HIPAA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIPAA authorization form for research</td>
<td>23a(1)</td>
<td>37</td>
<td>VA Form 10-0493 must be used for HIPAA authorizations for new studies. HIPAA authorization forms used in already approved studies do not have to be changed.</td>
</tr>
<tr>
<td><strong>Human Biological Specimens</strong></td>
<td>NA</td>
<td>53</td>
<td>Deleted from Handbook.</td>
</tr>
<tr>
<td><strong>Human Data</strong></td>
<td>NA</td>
<td>54</td>
<td>Deleted from Handbook. Refer to VHA Handbook 1200.12.</td>
</tr>
<tr>
<td>Topics (listed alphabetically)</td>
<td>Paragraph in 1200.05 version 11/12/2014</td>
<td>Paragraph in 1200.05 version 5/2/2012</td>
<td>Summary &amp; Rationale for Significant Change in VHA Handbook 1200.05 (November 12, 2014)</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------------------</td>
<td>----------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Informed Consent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contracting Firms</td>
<td>29f(1)(a) NA</td>
<td></td>
<td>The Privacy Officer must determine that there is appropriate authority to allow disclosure of PHI to contracting firms wishing to obtain consent from subjects or collect PII from subjects.</td>
</tr>
<tr>
<td>Informed Consent Document</td>
<td>16a 33a</td>
<td></td>
<td>Use of VA Form 10-1086 to document consent is no longer required by ORD. The written consent document must include all required elements and additional elements as approved by the IRB.</td>
</tr>
<tr>
<td>Informed Consent Document</td>
<td>16e(2)(b) 33c</td>
<td></td>
<td>The IRB can waive the signature of the individual obtaining consent on the IRB-approved consent form if no physical contact with the subject will occur.</td>
</tr>
<tr>
<td>Informed Consent Document</td>
<td>16e(1) 33a(2)</td>
<td></td>
<td>The IRB can approve the use of an electronic informed consent form provided ORD and VA requirements are met.</td>
</tr>
<tr>
<td>Informed Consent Document</td>
<td>16e(2)(c ) 33a</td>
<td></td>
<td>Numerous VA-specific items are no longer required to be included in the informed consent form.</td>
</tr>
<tr>
<td>Informed Consent Document/Consent for use of picture and/or voice</td>
<td>16f 55b</td>
<td></td>
<td>Use of VA Form 10-3203 is no longer required. However, the consent form must include information describing any photographs, video, and/or audio recordings that will be taken or obtained for research purposes.</td>
</tr>
<tr>
<td><strong>International Research</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secure/Remote access to VA data</td>
<td>26a(1) 56a</td>
<td></td>
<td>Secure remote use/access to data residing on VA servers in the US or Puerto Rico is not considered International Research.</td>
</tr>
<tr>
<td>Facility Director Approval</td>
<td>26c 56c</td>
<td></td>
<td>With the exception of Cooperative Studies Program activities, a waiver from the CRADO is no longer required to conduct international research. Approval from the Facility Director is required. For additional information on this topic, please refer to ORD's guidance document on Approval of International Research.</td>
</tr>
<tr>
<td><strong>Investigator Responsibilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject Outreach</td>
<td>NA 5m</td>
<td></td>
<td>Investigators are no longer required to perform subject outreach nor distribute the brochure, &quot;Volunteering in research - Here are some things you need to know&quot;.</td>
</tr>
<tr>
<td>Notice of Privacy Practices</td>
<td>24f NA</td>
<td></td>
<td>Investigators must provide notice of privacy practices to any non-veteran enrolled in an approved VA protocol (see VHA Handbook 1605.04).</td>
</tr>
<tr>
<td>Master List of Subjects</td>
<td>NA 9(1)(h)</td>
<td></td>
<td>Investigators are no longer required to maintain a master list of subjects enrolled in their research studies.</td>
</tr>
<tr>
<td>Flagging health records</td>
<td>NA 44</td>
<td></td>
<td>Investigators are no longer required to flag VHA health records of subjects enrolled in VA research.</td>
</tr>
<tr>
<td>Human subjects training</td>
<td>29a(4) 61a</td>
<td></td>
<td>Investigators and research staff are no longer required to complete good clinical practices (GCP) training. Specific information on training requirements can be found on <a href="http://vaww.research.cfde.webdev.va.gov/pride/training/default.cfm">http://vaww.research.cfde.webdev.va.gov/pride/training/default.cfm</a></td>
</tr>
<tr>
<td>Topics (listed alphabetically)</td>
<td>Paragraph in 1200.05 version</td>
<td>Summary &amp; Rationale for Significant Change in VHA Handbook 1200.05 (November 12, 2014)</td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>IRB Functions and Operations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRB Meeting Minutes</td>
<td>7(c) 28</td>
<td>ORD has removed the requirement that the IRB Chair sign the final IRB meeting minutes.</td>
<td></td>
</tr>
<tr>
<td>IRB Meeting Minutes</td>
<td>7(c) 28</td>
<td>ORD has removed the requirement that draft IRB meeting minutes be completed in three weeks. ORD emphasizes that the IRB meeting minutes should to completed in a timely manner for the R&amp;D Committee review.</td>
<td></td>
</tr>
<tr>
<td>IRB Meeting Minutes</td>
<td>7(c) 28</td>
<td>ORD has removed numerous VA-specific IRB minute requirements to harmonize VA with Common Rule requirements.</td>
<td></td>
</tr>
<tr>
<td>Communication with Investigators</td>
<td>8d 25a(1)</td>
<td>ORD’s requirement that the IRB’s notification letter be signed by the Chair or the voting IRB member who reviewed the research has been removed.</td>
<td></td>
</tr>
<tr>
<td>IRB of Record</td>
<td>5d(1) 5e</td>
<td>In addition to using a VA facility’s own IRB, the IRB of another VA facility, the VA Central IRB, or the IRB of its affiliated medical or dental school, a VA Facility can now also designate an IRB of another Federal Agency as its IRB of record. Approval from the CRADO is still required if a VA facility is changing its IRB of record.</td>
<td></td>
</tr>
<tr>
<td>IRB Audits</td>
<td>NA 29</td>
<td>This topic has been deleted from the handbook.</td>
<td></td>
</tr>
<tr>
<td>IRB Membership</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointment of VA members to another entity’s IRB</td>
<td>5d(2)(b) 7c</td>
<td>With the exception of the VA Central IRB and a Central IRB of another federal agency, research programs with 10 or more protocols must appoint two voting members to an external IRB. Research programs with less than 10 protocols can appointment one voting member and one alternate voting member.</td>
<td></td>
</tr>
<tr>
<td>Appointment of VA members to another entity’s IRB</td>
<td>5d(2)(b) 7c</td>
<td>Voting members appointed to the affiliate IRB must have at least 1/8th VA appointments. These VA members are no longer required to be scientific voting members.</td>
<td></td>
</tr>
<tr>
<td>Membership tenure for IRB Chairs</td>
<td>6n(2) 12q(2)</td>
<td>Appointment term for IRB Chairs has been increased to up to three years, renewable indefinitely.</td>
<td></td>
</tr>
<tr>
<td>ISO/PO Review</td>
<td>22e 38g</td>
<td>ISO/PO final review is required only after IRB approval. There is now flexibility as to whether the ISO/PO serve on the IRB or are advisory to the IRB as non-voting members or consultants.</td>
<td></td>
</tr>
<tr>
<td>Payment to Subjects</td>
<td>NA 59</td>
<td>Deleted from Handbook.</td>
<td></td>
</tr>
<tr>
<td>Topics (listed alphabetically)</td>
<td>Paragraph in 1200.05 version</td>
<td>Paragraph in 1200.05 version</td>
<td>Summary &amp; Rationale for Significant Change in VHA Handbook 1200.05 (November 12, 2014)</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pregnant Women, Human Fetuses, and Neonates</td>
<td>17d(4) 46</td>
<td>Women known to be pregnant may be enrolled in research if all the requirements outlined in 45 CFR 46.204 are met. Additionally, the Facility Director must certify that the facility has sufficient expertise in women’s health to conduct the proposed research if pregnant women are enrolled in interventions that are greater than minimal risk. For additional information on this topic, please refer to ORD’s guidance document on Conducting Research involving Pregnant Women.</td>
<td></td>
</tr>
<tr>
<td>Use of FDA Pregnancy Category D or X Drugs in women of childbearing potential</td>
<td>NA 46</td>
<td>A waiver from the CRADO for use of category D or X drugs in women of child bearing potential is no longer required.</td>
<td></td>
</tr>
<tr>
<td>Research on neonates</td>
<td>17c 45c(2)</td>
<td>Observational and/or retrospective studies involving neonates are now allowed. Intervventional studies on neonates continue to be prohibited in VA research.</td>
<td></td>
</tr>
<tr>
<td>Prisoners</td>
<td>18a 47b</td>
<td>A waiver from the CRADO continues to be required prior to enrolling prisoners in VA-approved research.</td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Events (SAEs)</td>
<td>NA 42</td>
<td>Deleted from handbook.</td>
<td></td>
</tr>
<tr>
<td>Student Research</td>
<td>28a 63a(1)</td>
<td>Trainees may not serve as PI/Co-PI on VA research studies.</td>
<td></td>
</tr>
<tr>
<td>Participation in VA research</td>
<td>28a 63a</td>
<td>In addition to those with an educational affiliate agreement with their VA facility, trainees directly appointed to a VA training program that has no external institutional sponsorship can serve as investigators on VA-approved research (e.g. VA Advanced Fellows).</td>
<td></td>
</tr>
</tbody>
</table>